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**IN THE UNITED STATES PATENT AND TRADEMARR OFFICE**

In re Application of: : Group: 1652  
BRUNO DONATINI :  
Serial No.: 10/069,803 :  
Filed: October 25, 2001 :  
For: NOVEL...COMPOSITIONS :

600 Third Avenue  
New York, N.Y. 10016  
September 9, 2003

**RULE 116 AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Responsive to the office action of May 6, 2003, please amend this application as follows:

**Amendments to the claims** begin on page 2 of this paper.

**Remarks** begin on page 8 of this paper.

## AMENDMENTS TO THE CLAIMS

### **Claim 1**(currently amended)

~~A Pharmaceutical~~ pharmaceutical and dietary composition based on mushrooms which contain as active ingredients at least one edible mushroom or part of mushrooms and 30 to 70% by weight of at least one ~~derivative of~~ basically substituted chitosan ~~selectd~~ selected from the group consisting of ~~acidic or cationically substituted~~ chitosan ~~derivatives and basically substituted chitosan derivatives,~~ succinamide, chitosan acetamide and chitosan tartramide.

### **Claims 2 to 7**(previously cancelled)

### **Claim 8** (currently amended)

~~A composition according to~~ The method of claim 1 ~~23,~~ wherein the chitosan is a basically substituted chitosan derivative ~~has~~ with a pH of between 7 and 12.

### **Claim 10** (previously cancelled)

### **Claim 11** (currently cancelled)

### **Claim 12** (previously cancelled)

**Claim 13** (currently amended)

~~A composition according to claim 1,~~ The method of claim 23, wherein the mushrooms are selected from the group consisting of *Armillaria mellea*, *Agaricus bisporus*, *bisporus*, *Boletus edulis*, *Cordyceps sinensis*, *Coriolus versicolor*, *Flammulina velutipes*, *Ganoderma lucidum*, *Hecicum erinaceus*, *Hypsizygus marmoreus*, *Auricularia auricula-Judae*, *Phellinus linteus*, *Pleurotus ostreatus*, *Grifola frondosa*, *Agaricus campestris*, *Lentinus edodes*, *Tremela fuciformis*, and *Volvaria volvacea*.

**Claim 14** (currently cancelled)

**Claim 15** (currently amended)

A method according to claim 14 23 wherein the composition is in the form of cakes or biscuits.

**Claim 16** (currently amended)

~~A pharmaceutical or dietetic composition as defined in claim 1~~ The method of claim 23, wherein the ~~acidic or cationically substituted~~ chitosan is obtained ~~in~~ by reacting chitosan with an organic acid selected from the group consisting of acetic acid, lactic acid, succinic acid, tartaric acid, ascorbic acid, citric acid, glutamic acid, methanesulphonic acid and ethanesulfonic acid.

**Claim 17** (currently amended)

~~A pharmaceutical or dietetic composition according to claim 1~~ The method of claim 23, wherein the chitosan is an antionically-substituted chitosan derivative is ~~that~~ obtained by contacting ascorbic acid or lactic acid ~~to~~ with chitosan.

**Claim 18** (currently amended)

~~A pharmaceutical or dietetic composition according to claim 1~~ The method of claim 23, wherein the chitosan is anionically substituted chitosan ~~has~~ with a pH value lower than 6.

**Claim 19** (currently amended)

~~A pharmaceutical composition~~ The method of claim 23 wherein the chitosan ~~derivative~~ is a mixture of an anionically-substituted chitosan and basically-substituted chitosan.

**Claim 20** (currently amended)

~~A pharmaceutical or dietetic composition according to claim 1~~ The method of claim 23, wherein the ~~basically substituted~~ chitosan is a N-alkylcarboxamide of chitosan wherein the alkyl ~~group~~ has ~~from~~ 2 to 6 carbon atoms.

**Claim 21** (currently amended)

~~A pharmaceutical composition according to claim 1~~ The method of claim 23,  
wherein the ~~basically substituted~~ chitosan is selected from the group consisting of  
chitosan succinamide, chitosan acetamide and chitosan tartramide.

**Claim 22** (currently amended)

A pharmaceutical or dietetic composition according to claim 1, wherein the part  
of mushrooms ~~such as the mycelia~~ are used in the fresh form or in the form of a dry  
extract.

**Claim 23** (currently added)

A method of chelating contaminants and extending the release of the  
therapeutically active ingredients in the duodenum, the jejunum, the ileum and the colon,  
comprising administering a pharmaceutical and/or dietary composition which contains at  
least one edible mushroom or parts of mushroom having therapeutic properties and 30 to  
70% by weight of chitosan combined or admixed with a diluting agent or a non-toxic  
vehicle, to patients having obesity, hypercholesterolemia, diabetes, memory disturbances  
and asthma.

**Claim 24** (currently added)

The method of claim 23, wherein the chitosan is selected from the group consisting of acidic or cationically-substituted chitosan and basically-substituted chitosan.

**Claim 25** (currently added)

A pharmaceutical and dietary composition based on mushrooms which contain as active ingredient at least one edible mushroom, or part of mushrooms, and a chelating agent for contaminating soil substances constituted of a mixture of basically-substituted chitosan derivative and acid addition derivative of chitosan.

**Claim 26** (currently added)

A pharmaceutical and dietary composition according to claim 25 wherein the composition contains from 30 to 70% by weight of the mixture of one basically-substituted derivative of chitosan and an acid-addition derivative of chitosan.

**Claim 27** (currently added)

A pharmaceutical and dietary composition according to claim 25 wherein the composition contains 25% by weight of an acid addition salt of chitosan.

**Claim 28** (currently added)

A pharmaceutical and dietary composition according to claim 25 wherein the composition contains 25% by weight of a basically-substituted chitosan.

**Claim 29** (currently added)

A pharmaceutical and dietary composition according to claim 25 wherein basically-substituted chitosan is selected from the group consisting of chitosan succinamide, chitosan acetamide and chitosan tartramide.

**Claim 30** (currently added)

A pharmaceutical and dietary composition according to claim 25 wherein the mushrooms are selected from the group consisting of *Armillaria mellea*, *Agaricus bisporus*, *Boletus edulis*, *Cordyceps sinensis*, *Coriolus versicolor*, *Flammulina velutipes*, *Ganoderma lucidum*, *Hericium erinaceus*, *Hypsizygus marmoreus*, *Auricularia auricula-Judae*, *Phellinus linteus*, *Pleurotus ostreatus*, *Grifola frondosa*, *Agaricus campestris*, *Lentinus edodes*, *Tremela fuciformis* and *Volvaria volvacea*.